JC07 Rec'd PCT/PTO 21 DEC 2001

FORM PTO-1390) (REV. 9-2001) U S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE **TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371**		ATTORNEY'S DOCKET NUMBER **635.40829X00 filed December 21, 2001** U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/018797
INTERNATIONAL APPLICATION NO **PCT/CH00/00334**	INTERNATIONAL FILING DATE **June 20, 2000**	PRIORITY DATE CLAIMED **June 25, 1999**

TITLE OF INVENTION
DEVICE FOR CARRYING OUT PROTON THERAPY

APPLICANT(S) FOR DO/EO/US
PEDRONI, EROS

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371(c)(2)))
   a. ☐ is transmitted hereto (required only if not communicated by the International Bureau).
   b. ☒ has been communicated by the International Bureau.
   c. ☐ is not required, as the application was filed in the United States Receiving Office(RO/US)
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
   a. ☒ is attached hereto.
   b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. ☐ are attached hereto (required only if not communicated by the International Bureau).
   b. ☐ have been communicated by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A FIRST preliminary amendment.
14. ☐ A SECOND or SUBSEQUENT preliminary amendment.
15. ☒ A substitute specification.
16. ☒ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: **Figs. 1-4, Credit Card Payment Form, International Publication No. WO 01/00276, PCT Request Form, International Preliminary Examination Report w/amended sheets**

U.S. APPLICATION NO (If known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
10/018797	PCT/CH00/00334	635.40829X00

21. The following fees are submitted:				CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492(a) (1) - (5)):					
☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1040.00**					
☒ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO **$890.00**					
☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$740.00**					
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$710.00**					
☐ International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**					
ENTER APPROPRIATE BASIC FEE AMOUNT =				$890.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	$	
Total Claims	- 20 =		x **$18.00**	$	
Independent Claims	- 3 =		x **$84.00**	$	
MULTIPLE DEPENDENT CLAIMS(S) (if applicable)			+ $280.00	$	
TOTAL OF ABOVE CALCULATIONS =				$890.00	
☐ Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by ½. +				$	
SUBTOTAL =				$890.00	
Processing fee of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$	
TOTAL NATIONAL FEE =				$890.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$	
TOTAL FEES ENCLOSED =				$890.00	
				Amount to be refunded:	$
				charged:	$

a. ☐ A check in the amount of $______ to cover the fees is enclosed.

b. ☐ Please charge my Deposit Account No. 01-2135 in the amount of $______ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposition Account No. **01-2135**. A duplicate copy of this sheet is enclosed.

d. ☒ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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28,577
REGISTRATION NO.

10/018797
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Eros PEDRONI

Serial No.: New Application

Filed: December 21, 2001

For: DEVICE FOR ADMINISTERING A PROTON THERAPY

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, D.C. 20231

December 21, 2001

SIR:

The following amendments and remarks are submitted in the above-identified application at the time of filing.

IN THE SPECIFICATION

A Substitute Specification is enclosed in which appropriate headings have been added. A reference to the related, parent international application has also been added at the beginning of the Substitute Specification. No new matter has been added. A copy of the Substitute Specification marked up with the additions underlined and the deletions in brackets is also enclosed to show the changes

made from the text of the English translation of the international application specification as amended.

An Abstract of Disclosure is provided on a separate sheet filed herewith. It is requested that the Abstract be included as part of the specification.

IN THE CLAIMS

Please cancel claims 1-14 and add new claims 15-28.

15. Apparatus for treating a patient using proton therapy, comprising:

a proton beam guiding device employing magnets, quadrupoles, and an end-mounted proton beam guiding and control device with an exit window for guiding or directing the proton beam to the treatment spot in the patient;

a controllably movable patient table for moving the patient to the desired position relative to the proton beam;

wherein the proton beam guiding and control device is located so as to be turnable or rotatable by turning or rotating about a horizontal axis in such a way that the patient table located in essentially the plane of the horizontal axis of rotation remains accessible from the side; and

wherein the patient table is rotatable in a horizontal plane running essentially through the axis of rotation of the proton beam guiding device or

parallel to it and displaced by a small deviation around an axis which runs essentially through the isocenter of the apparatus, which isocenter is formed by the intersection of the proton beam with the horizontal axis of rotation or with the intersection by approximation of the beam with the horizontal axis of rotation.

16. Apparatus according to claim 15, wherein the beam guiding and control device is arranged to be turnable or rotatable by at least 135° upwards and downwards from a horizontal plane running essentially through the horizontal axis of rotation.

17. Apparatus according to claim 15, wherein the beam guiding and control device is arranged to be rotatable about the horizontal axis of rotation from a vertical plane running essentially through the horizontal axis of rotation by an angle of 90° from the side of the vertical plane on which the patient table is located up to an angle of approximately 180° on the opposite side of the vertical plane.

18. Apparatus according to claim 15, wherein the patient table is arranged to be rotatable or movable in a region of the horizontal plane through which the beam guiding and control device is not movable, or which region lies opposite another region through which the beam guiding and control device is movable.

19. Apparatus according to claim 15, wherein the patient table is rotatable about an axis in an end-mounted region on the patient table.

20. Apparatus according to claims 15, wherein the patient table is arranged to be slidable or movable in its longitudinal axis.

21. Apparatus according to claims 15, wherein the patient table is designed to be additionally rotatable about an axis running vertically in essentially the center region of the table, to be movable in a direction transverse to the longitudinal axis, and also to be adjustable in height.

22. Apparatus according claim 15, further comprising a proton beam penetration depth adjustment device located in front of the apparatus before the

magnets and quadrupoles, the proton beam penetration depth adjustment device comprising a system of plates or blades movable in or through the proton beam so as to control or restrict the energy and the associated penetration depth of the proton beam in the patient.

23. Apparatus for treating a patient using proton therapy, comprising:

a proton beam guiding device employing magnets, quadrupoles, and an end-mounted proton beam guiding and control device with an exit window for directing the proton beam to the treatment spot in the patient;

a controllably movable patient table for moving the patient to the desired position relative to the proton beam;

wherein the exit window or a covering housing which is end-mounted on the proton beam guiding and control device and forms the exit window, is provided which is movement-coupled with the patient table during treatment such that during treatment of the patient discrete movements effected by the patient table are synchronously reproduced by the exit window or covering housing.

24. Apparatus according to claim 23, further comprising an additional control device for coupling the motion of the patient table with the exit window or covering housing during treatment of a patient.

25. A method for treating a patient using proton therapy, the method comprising:

directing a proton beam to a treatment spot in a patent using an apparatus comprising a proton beam guiding device employing magnets, quadrupoles, and an end-mounted proton beam guiding and control device with an exit window for guiding or directing the proton beam to the treatment spot in the patient; and a controllably movable patient table for moving the patient to the desired position relative to the proton beam; and

wherein the method includes positioning a person lying on the patient table by moving the patient table and proton beam guiding and control device of the apparatus such that the proton beam is directed to the treatment spot in the patient, and wherein the patient table remains accessible at all times from one side.

26. The method according to claim 25, wherein the moving includes positioning the proton beam guiding and control device and the patient table around one axis — the proton beam guiding and control device by turning or rotating about a horizontal axis of rotation and the patient table by turning in a horizontal plane running essentially through the horizontal axis of rotation or parallel to this and arranged so as to be displaced by a small deviation — which one axis runs essentially through the isocenter of the apparatus, which isocenter is formed by the intersection of the proton beam with the axis of rotation or with the intersection by approximation of the beam with the axis of rotation.

27. The method according to claim 25, further comprising controlling or restricting the energy, and associated with this, the penetration depth of the proton beam in the patient by means of a proton beam penetration adjustment device located in front of the apparatus before the magnets and quadrupoles, which adjustment device comprises a system of plates or blades movable in or through the proton beam.

28. The method according to claim 25, wherein the treating includes destroying a malignant organ or tumor in a human body.

REMARKS

By the above amendments, the specification has been amended, an Abstract has been added, claims 1-14 have been canceled and new claims 15-28 have been added. An Information Disclosure Statement is also being filed herewith under separate cover letter citing the International Search Report in the parent International Application and the references referred to in the Search Report.

An early action on the merits is requested.

Please charge any shortage in the fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account No. 01-2135 (500.36515VX1) and please credit any excess fees to such deposit account.

Respectfully submitted,

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ABSTRACT OF THE DISCLOSURE

An apparatus for carrying out proton therapy on a patient comprises a proton beam guiding device using magnets, quadrupoles, and an end-mounted device for proton beam guiding and control device with an exit window for guiding or directing the proton beam to the treatment spot in the patient. A patient table of the apparatus can be moved in a controlled manner in such a way that the patient can be placed in a desired position with respect to the proton beam. The proton beam guiding and controlling device can be turnably or rotatably mounted around a horizontal axis of rotation in such a way that the patient table which is arranged approximately on the plane of the axis of rotation remains accessible from one side at all moments for the person treating the patient. The patient table can be displaced slightly on a horizontal plane, extending inside of the axis of rotation or parallel thereto, about an axis which runs approximately through the isocenter of the device, wherein the isocenter is formed by the intersection of the proton beam with the axis of rotation or the approximate point where the beam intersects with the axis of rotation. The apparatus is particularly suitable for use in the destruction of a sick organ or tumor in the human body.

Substitute Specification

Device for Administering a Proton Therapy

Related Application

This application is a Section 371 filing based on International Application PCT/CH00/00334 filed June 20, 2000, the priority of which is claimed under 35 USC §120. A claim for priority under 35 USC §119 is in turn made to Switzerland Application No. 1180/99, filed June 25, 1999.

Field

This invention relates to a device for administering proton therapy to human patients as well as various improvements designed to increase safety, to improve and simplify process control, to enhance patient acceptability, and also to allow the device to be constructed to smaller dimensions; the invention also relates to an application of the device

Background

Proton therapy, especially that intended for the treatment of cancers, is becoming increasingly important since it entails significant advantages in

comparison with the photon-radiation therapy in widespread use.

Although equipment for administering proton therapy has been known since the mid-fifties in the U.S., up to now such therapies have been utilized worldwide only at a few centers such as research institutions. This circumstance is due first to the fact that proton accelerators required are still quite expensive, and secondly to the fact that the proton therapy equipment necessary for administering an efficient and safe therapy is quite large and complex. The first and only purely hospital-based proton therapy device is located in the U.S. at the Loma Linda University Medical Center in California. Additional units are in the process of being put into operation in Boston (U.S.) and Kashiwa (Japan).

Unlike the above device at the Loma Linda University Medical Center in which the proton therapy is performed using a so-called scattering method, a proton therapy device was developed at the Paul Scherrer Institute in Würlingen, Switzerland, which utilizes the so-called spot-scanning method. In this connection, reference is made to the article by Eros Pedroni et al. in Med. Phys. 22 (1), January 1995, pages 37—53 with the title 'The 200-Mev

Proton Therapy Project at the Paul Scherrer Institute: Conceptual Design and Practical Realization." This article refers to the fundamental principle of the above-mentioned spot-scanning method and to a device described using the term 'gantry," with which device proton therapy has now been administered to patients for about three years . Although the outside dimensions of the device at the Paul Scherrer Institute were able to be reduced relative to the device at the Loma Linda University Medical Center by using the so-called spot-scanning method, this device still has a diameter of about 4 m, and has the additional disadvantage that access to patients during treatment is unsatisfactory. A detailed description of the device at the Paul Scherrer Institute may be dispensed with by citing the above reference in the literature, which reference is an integral part of the present patent application.

In European Patent Applications EP 0 864 337 and EP 0 911 064, similar arrangements for treating a patient by proton therapy are described, which are partially based on the device developed at the Paul Scherrer Institute or describe similar or the same treatment methods.

The preferred position for a patient is the supine position so as to preclude any deformation of the organs during treatment. Therapy must therefore allow accessibility from all sides and encompass the entire human body; for this reason, the generally known proton therapy devices, including that at the Paul Scherrer Institute, are designed so that the entire proton beam guiding device housing is rotatable 360° about a central axis around the so-called patient table, with the result that the device may have a diameter of between 4 and 12 meters. Especially when treating a patient from below, the proton beam guiding device must be moved under the patient table, or the patient table must be raised to a position several meters above the actual level of the working base. The resulting specific disadvantages may also be found in the above-cited literature reference on page 49 in chapter IV, D4 which cites the problems entailed by raising the patient table in this way. This positioning process is critical, and in the event the device experiences an accident during treatment, a special crane device is required to extract or manage the patient. While this disadvantage may be alleviated by providing a relatively deep shaft under the patient table, this approach creates a risk of accidents, such as the person treatment the patient falling into this shaft.

Summary

The object of this invention is thus to propose measures by which the operation of proton therapy may be simplified and made safer, and in which preferably the outside dimensions of the device may be reduced. This object is achieved by the proton therapy device or apparatus of the invention, and by means of a method for treating a patient according to the invention using the proton therapy apparatus.

The invention proposes that a proton beam guiding and control device, or a proton beam guiding device housing located in the treatment arrangement, not be rotatable by a full 360° around a patient table, unlike the "gantry" of the Paul Scherrer Institute, described in the literature, but that the rotational movement be limited to approximately 270°. Here the rotation occurs essentially about a horizontal axis of rotation, in which axis of rotation generally a controllably movable patient table is located in the starting position. This limitation to 270° results in a region through which the beam guiding and control device is not freely movable, in which region the patient table is freely movable and always readily accessible. It is this accessibility to the patient table in particular which represents an essential improvement

provided by this invention since the person providing treatment may always access the patient without danger or obstruction.

The result of this preferred arrangement of the proton beam guiding and control device in which the device is rotatable starting from the horizontal plane running essentially through the axis of rotation both upwards and downwards by approximately 135° about the axis of rotation, or from - 90° to +180° from the vertical, is that the patient table is readily accessible from the opposite side. The patient table is thus freely movable within the above-mentioned horizontal plane or within a horizontal plane designed to run nearly parallel to this plane - for example, specifically rotatable by at least 180° about an axis which runs essentially through the isocenter of the proton beam guiding and control device. The isocenter is formed on the one hand by the proton beam exiting the proton beam guiding and control device, and on the other hand by the axis of rotation about which this device is rotatable.

The result of this arrangement according to the invention is first of all, as already mentioned, that the patient table is always readily accessible, and secondly that despite this accessibility treatment of the patient from all sides

is possible since first of all treatment both from above and below is ensured, as is treatment from both sides, the treatment being enabled by rotating the patient table by 180°.

Preferred variant embodiments of the arrangement according to the invention are characterized in the dependent claims.

To provide a fuller understanding of the invention, an example of a proton beam treatment device according to the invention is described in more detail based on Figs. 1—3.

Brief Description of the Drawings

Figure 1 is a perspective view of a proton beam treatment device for treatment of a patient from the side.

Figure 2 shows the device in Figure 1 for treatment of a patient from above.

Figure 3 shows the device in Figure 1 for treatment of a patient from below.

Detailed Description

Figure 1 shows in schematic and simplified form a device or apparatus 1 for treating a patient using proton beam therapy. Here the proton beam 3 is directed by quadrupoles 5 and magnets 7 to the actual end-mounted proton beam guiding and control device 9. Located on the front face of this proton beam guiding and control device is an exit window 11 or so-called 'nozzle" through which the proton beam exits and is directed to the patient. The proton beam may be deflected horizontally within a narrowly limited angle by an additional deflection magnet arrangement 6, also called a 'sweeper magnet." At the same location, the drawings show a second 'sweeper magnet" which may be used as an option to effect a rapid magnetic motion of the beam — but one which is limited by the aperture of the 90° magnet. Also located in the region of exit window 11 and not visible in Figure 1 is a penetration depth adjustment device, also called a 'range shifter," by which the penetration depth of the proton beam into the body of the patient may be set. It is important here to again refer to the article by Pedroni et al. cited in the preamble which describes the basic principles of operation for a proton beam therapy device such as the so-called "gantry" at the Paul Scherrer Institute.

Also shown in Figure 1 is a guide rail 13 on which is arranged the proton beam guiding and control device 9 so as to be movable about a central axis of rotation. Protruding through lateral shielding guides 15, the exit window 11 moves in a slit-like opening 17 along mounting device 13 when the guiding and control device (9) is moved.

A patient table 21 is arranged to lie in a horizontal plane, running essentially through the axis of rotation of the guiding and control device. This table is movable about an axis of rotation and on a mounting device 23 along a guide 24, this guide being located on a working platform 25. The rotation of patient table 21 proceeds preferably here about an axis of rotation which runs essentially through the head region 27 of patient table 21, and which axis of rotation runs mainly through the region of the so-called isocenter of the device. It is of course possible to have the horizontal plane in which the patient table 21 is located also run parallel a certain distance above or below the horizontal plane through which the rotational axis of proton beam guiding and control device 9 runs. This distance should be restricted, however, so as to ensure that proper treatment is possible from above and

below, and additionally to allow the patient table to be capable of being accessed at a suitable height from working platform 25 by the person providing treatment. It is of course also possible to have patient table 21 be arranged on mounting device 23 so as to be both adjustable vertically and slidable in the longitudinal and transverse axes of the table.

The rotatability of the patient table should encompass an angle of at least 180°, although it is clearly evident from Figure 1 that an angle greater than 180° is not feasible for reasons of design and is also not necessary. According to another special variant embodiment, it is also possible to design the patient table to be rotatable about another axis of rotation, for example, around a vertical axis of rotation running through the center of the table. This rotation is necessary or useful, for example, when a patient is to be treated in the leg region and this region must thus be aligned with the isocenter of the device to allow, for example, a tumor in one leg to be treated accordingly by the proton beam.

Figure 2 shows the same device as in Figure 1 with beam guiding and control device 9 in the top orientation. In other words, in the arrangement of

Figure 2 the proton beam treatment is administered from above, while in addition the patient table is in a position different from that in Figure 1. In addition, Figure 2 clearly shows that the patient table is slidable in the longitudinal axis of the table.

Finally Figure 3 shows yet another position attainable by beam guiding and control device 9 where treatment of the patient is administered from below.

The fundamental advantage of the device described according to the invention over the known 'gantry" at the Paul Scherrer Institute is immediately evident in the fact that the patient table, for example, does not need to be raised significantly to administer treatments from below and that as a consequence accessibility to the patient table for the person providing treatment is always ensured. This feature has advantages not only for a patient receiving treatment but also for a person providing treatment since with the device according to the invention there is no longer any risk of accidentally falling into a shaft.

An additional problem associated with existing proton treatment devices is

encountered in the region of the exit window of the proton beam housing, also called the ‘nozzle” in English and in technical parlance. Located in the region of this exit window in the device described in the introduction above is a penetration depth adjustment device, also called a ‘range shifter” with which the penetration depth of the proton beam is controlled very precisely since the energy required to destroy a malignant organ or tumor is released precisely at the end of the range of the proton beam.

In practice it has been found that the proton beam is disturbed by the air gap between the so-called ‘range shifter” and the patient, thereby degrading the precision of beam control at least slightly.

For this reason, the invention also proposes locating this adjustment device for modifying the range of the proton beam, or the so-called ‘range shifter,” no longer in the region of the output window or the so-called ‘nozzle” on the proton beam guiding housing, but instead before the entry of the proton beam into the guiding housing in which the proton beam is guided, in known fashion, to the patient and to the so-called ‘spot” receiving treatment. With respect to Figure 1, this means that the so-called ‘range shifter” is no longer

located in the region of exit window 11 but placed before the treatment arrangement 1, as Figure 4 shows schematically, specifically with reference number 31.

Placing the so-called "range shifter" before the following proton beam guiding device within the treatment arrangement does, however, have the effect that in conjunction with this design magnetic arrangements 7, or the magnet arrangement in the end-mounted proton beam guiding and control device housing 9, must be made variable in order to compensate for an increased or attenuated energy of the proton beam so that the proton beam may ultimately be in turn directed to the desired spot in the patient. However, this is no problem using the currently known process controls or known computer controls, while on the other hand the above-cited problems connected with the precision of beam control may be significantly improved by simplifying the design of the exit window.

The usual procedure for the required destruction of the malignant cells in an organ or in a human body is to move the patient table relative to the proton beam guiding housing in discrete steps so as to allow the proton beam to

scan the entire region in the organ or human body point by point. This motion of the patient table is necessary since the 'sweeper magnet" and 'range shifter" move the proton beam only in two directions, or two—dimensionally, so that the patient table must be designed to be movable to accommodate the spatial treatment of a region in a patient, or to accommodate the third dimension. With the selected spot—scanning method, this motion of the patient table is not continuous but occurs, as mentioned, in discrete steps. This discrete motion is often viewed as disadvantageous or awkward, especially by the attending physicians or persons providing treatment.

For this reason, another variant embodiment of the proton therapy device according to the invention proposes a covering housing in the region of the exit window or so-called "nozzle" in which all the devices required for dosing and control or shielding, and elements for controlling the proton beam, are located out of sight. With respect to the motion, this housing itself is coupled to the patient table through a control device such that the discrete movements of the table are also effected by this covering housing and for the patient no relative motion with respect to the proton beam guiding housing

occurs. An additional advantage of including such a covering housing is the fact that the relative position of a contact-hazard-protection device, which may be integrated with the housing, always ensures optimum protection in the event the patient table is to be moved relative to the exit window or the 'nozzle." Such a protection device may thus be located within the housing where it can interrupt the proton beam within fractions of a millisecond.

The advantage of including such a covering housing is also the fact that, for example, the collimators and compensators required for concentrating and focusing the proton beam in other known devices, for example, those using the so-called scattering method, may be located in such a housing. The controlled coupling of the covering with the patient table ensures in this case that even when the patient table is moved the proton beam always remains directed at the proper spot in the body of the patient body.

With respect to Figure 1, this means that the housing 11 of the exit window, shown schematically, is not attached to proton beam guiding and control device 9 but is controlled to move also synchronously with the movements of the patient table. It is possible here to couple the movements of covering

housing 11 with those of patient table 21 by using a control device so that no relative motions between the housing and the table take place when patient table 21 is moved during treatment of the patient.

The improvements proposed according to the invention for a proton beam treatment device, especially one utilizing the spot-scanning method such as the so-called ‘gantry” at the Paul Scherrer Institute, result in significant simplifications in the operation of the device as well as enhancements in the safety and user acceptability of the device, both for patients as well as for the operating personnel.

Marked-up Version

Device for Administering a Proton Therapy

Related Application

This application is a Section 371 filing based on International Application PCT/CH00/00334 filed June 20, 2000, the priority of which is claimed under 35 USC §120. A claim for priority under 35 USC §119 is in turn made to Switzerland Application No. 1180/99, filed June 25, 1999.

Field

This invention relates to a device for administering proton therapy to human patients as well as various improvements designed to increase safety, to improve and simplify process control, to enhance patient acceptability, and also to allow the device to be constructed to smaller dimensions; the invention also relates to an application [or a] of the device

Background

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comparison with the photon-radiation therapy in widespread use.

Although equipment for administering proton therapy has been known since the mid-fifties in the U.S., up to now such therapies have been utilized worldwide only at a few centers such as research institutions. This circumstance is due first to the fact that proton accelerators required are still quite expensive, and secondly to the fact that the proton therapy equipment necessary for administering an efficient and safe therapy is quite large and complex. The first and only purely hospital-based proton therapy device is located in the U.S. at the Loma Linda University Medical Center in California. Additional units are in the process of being put into operation in Boston (U.S.) and Kashiwa (Japan).

Unlike the above device at the Loma Linda University Medical Center in which the proton therapy is performed using a so-called scattering method, a proton therapy device was developed at the Paul Scherrer Institute in Würlingen, Switzerland, which utilizes the so-called spot-scanning method. In this connection, reference is made to the article by Eros Pedroni et al. in Med. Phys. 22 (1), January 1995, pages 37—53 with the title 'The 200-Mev

Proton Therapy Project at the Paul Scherrer Institute: Conceptual Design and Practical Realization." This article refers to the fundamental principle of the above-mentioned spot-scanning method and to a device described using the term 'gantry," with which device proton therapy has now been administered to patients for about three years . Although the outside dimensions of the device at the Paul Scherrer Institute were able to be reduced relative to the device at the Loma Linda University Medical Center by using the so-called spot-scanning method, this device still has a diameter of about 4 m, and has the additional disadvantage that access to patients during treatment is unsatisfactory. A detailed description of the device at the Paul Scherrer Institute may be dispensed with by citing the above reference in the literature, which reference is an integral part of the present patent application.

In European Patent Applications EP 0 864 337 and EP 0 911 064, similar arrangements for treating a patient by proton therapy are described, which are partially based on the device developed at the Paul Scherrer Institute or describe similar or the same treatment methods.

The preferred position for a patient is the supine position so as to preclude any deformation of the organs during treatment. Therapy must therefore allow accessibility from all sides and encompass the entire human body; for this reason, the generally known proton therapy devices, including that at the Paul Scherrer Institute, are designed so that the entire proton beam guiding device housing is rotatable 360° about a central axis around the so-called patient table, with the result that the device may have a diameter of between 4 and 12 meters. Especially when treating a patient from below, the proton beam guiding device must be moved under the patient table, or the patient table must be raised to a position several meters above the actual level of the working base. The resulting specific disadvantages may also be found in the above-cited literature reference on page 49 in chapter IV, D4 which cites the problems entailed by raising the patient table in this way. This positioning process is critical, and in the event the device experiences an accident during treatment, a special crane device is required to extract or manage the patient. While this disadvantage may be alleviated by providing a relatively deep shaft under the patient table, this approach creates a risk of accidents, such as the person treatment the patient falling into this shaft.

Summary

The object of this invention is thus to propose measures by which the operation of proton therapy may be simplified and made safer, and in which preferably the outside dimensions of the device may be reduced.

[According to the invention, this] This object is achieved by [a] the proton therapy device [particularly according to Claim 1] or apparatus of the invention, and by means of a method for treating a patient according to the invention using the proton therapy [device according to Claim 11] apparatus.

The invention proposes that a proton beam guiding and control device, or a proton beam guiding device housing located in the treatment arrangement, not be rotatable by a full 360° around a patient table, unlike the "gantry" of the Paul Scherrer Institute, described in the literature, but that the rotational movement be limited to approximately 270°. Here the rotation occurs essentially about a horizontal axis of rotation, in which axis of rotation generally a controllably movable patient table is located in the starting position. This limitation to 270° results in a region through which the beam guiding and control device is not freely movable, in which region the patient

table is freely movable and always readily accessible. It is this accessibility to the patient table in particular which represents an essential improvement provided by this invention since the person providing treatment may always access the patient without danger or obstruction.

The result of this preferred arrangement of the proton beam guiding and control device in which the device is rotatable starting from the horizontal plane running essentially through the axis of rotation both upwards and downwards by approximately 135° about the axis of rotation, or from - 90° to +180° from the vertical, is that the patient table is readily accessible from the opposite side. The patient table is thus freely movable within the above-mentioned horizontal plane or within a horizontal plane designed to run nearly parallel to this plane - for example, specifically rotatable by at least 180° about an axis which runs essentially through the isocenter of the proton beam guiding and control device. The isocenter is formed on the one hand by the proton beam exiting the proton beam guiding and control device, and on the other hand by the axis of rotation about which this device is rotatable.

The result of this arrangement according to the invention is first of all, as

already mentioned, that the patient table is always readily accessible, and secondly that despite this accessibility treatment of the patient from all sides is possible since first of all treatment both from above and below is ensured, as is treatment from both sides, the treatment being enabled by rotating the patient table by 180°.

Preferred variant embodiments of the arrangement according to the invention are characterized in the dependent claims.

[Applications of the arrangement according to the invention are characterized in Claims 11 *et seq.*]

To provide a fuller understanding of the invention, an example of a proton beam treatment device according to the invention is described in more detail based on Figs. 1—3[, wherein:].

Brief Description of the Drawings

Figure 1 is a perspective view of a proton beam treatment device for

treatment of a patient from the side.

Figure 2 shows the device in Figure 1 for treatment of a patient from above.

Figure 3 shows the device in Figure 1 for treatment of a patient from below.

Detailed Description

Figure 1 shows in schematic and simplified form a device or apparatus 1 for treating a patient using proton beam therapy. Here the proton beam 3 is directed by quadrupoles 5 and magnets 7 to the actual end-mounted proton beam guiding and control device 9. Located on the front face of this proton beam guiding and control device is an exit window 11 or so-called 'nozzle" through which the proton beam exits and is directed to the patient. The proton beam may be deflected horizontally within a narrowly limited angle by an additional deflection magnet arrangement 6, also called a 'sweeper magnet." At the same location, the drawings show a second 'sweeper magnet" which may be used as an option to effect a rapid magnetic motion of the beam — but one which is limited by the aperture of the 90° magnet. Also located in the region of exit window 11 and not visible in Figure 1 is a

penetration depth adjustment device, also called a 'range shifter," by which the penetration depth of the proton beam into the body of the patient may be set. It is important here to again refer to the article by Pedroni et al. cited in the preamble which describes the basic principles of operation for a proton beam therapy device such as the so-called "gantry" at the Paul Scherrer Institute.

Also shown in Figure 1 is a guide rail 13 on which is arranged the proton beam guiding and control device 9 so as to be movable about a central axis of rotation. Protruding through lateral shielding guides 15, the exit window 11 moves in a slit-like opening 17 along mounting device 13 when the guiding and control device (9) is moved.

A patient table 21 is arranged to lie in a horizontal plane, running essentially through the axis of rotation of the guiding and control device. This table is movable about an axis of rotation and on a mounting device 23 along a guide 24, this guide being located on a working platform 25. The rotation of patient table 21 proceeds preferably here about an axis of rotation which runs essentially through the head region 27 of patient table 21, and which

axis of rotation runs mainly through the region of the so-called isocenter of the device. It is of course possible to have the horizontal plane in which the patient table 21 is located also run parallel a certain distance above or below the horizontal plane through which the rotational axis of proton beam guiding and control device 9 runs. This distance should be restricted, however, so as to ensure that proper treatment is possible from above and below, and additionally to allow the patient table to be capable of being accessed at a suitable height from working platform 25 by the person providing treatment. It is of course also possible to have patient table 21 be arranged on mounting device 23 so as to be both adjustable vertically and slidable in the longitudinal and transverse axes of the table.

The rotatability of the patient table should encompass an angle of at least 180°, although it is clearly evident from Figure 1 that an angle greater than 180° is not feasible for reasons of design and is also not necessary. According to another special variant embodiment, it is also possible to design the patient table to be rotatable about another axis of rotation, for example, around a vertical axis of rotation running through the center of the table. This rotation is necessary or useful, for example, when a patient is to

be treated in the leg region and this region must thus be aligned with the isocenter of the device to allow, for example, a tumor in one leg to be treated accordingly by the proton beam.

Figure 2 shows the same device as in Figure 1 with beam guiding and control device 9 in the top orientation. In other words, in the arrangement of Figure 2 the proton beam treatment is administered from above, while in addition the patient table is in a position different from that in Figure 1. In addition, Figure 2 clearly shows that the patient table is slidable in the longitudinal axis of the table.

Finally Figure 3 shows yet another position attainable by beam guiding and control device 9 where treatment of the patient is administered from below.

The fundamental advantage of the device described according to the invention over the known 'gantry" at the Paul Scherrer Institute is immediately evident in the fact that the patient table, for example, does not need to be raised significantly to administer treatments from below and that as a consequence accessibility to the patient table for the person providing

treatment is always ensured. This feature has advantages not only for a patient receiving treatment but also for a person providing treatment since with the device according to the invention there is no longer any risk of accidentally falling into a shaft.

An additional problem associated with existing proton treatment devices is encountered in the region of the exit window of the proton beam housing, also called the ‘nozzle” in English and in technical parlance. Located in the region of this exit window in the device described in the introduction above is a penetration depth adjustment device, also called a ‘range shifter” with which the penetration depth of the proton beam is controlled very precisely since the energy required to destroy a malignant organ or tumor is released precisely at the end of the range of the proton beam.

In practice it has been found that the proton beam is disturbed by the air gap between the so-called ‘range shifter” and the patient, thereby degrading the precision of beam control at least slightly.

For this reason, the invention also proposes locating this adjustment device

for modifying the range of the proton beam, or the so-called 'range shifter," no longer in the region of the output window or the so-called 'nozzle" on the proton beam guiding housing, but instead before the entry of the proton beam into the guiding housing in which the proton beam is guided, in known fashion, to the patient and to the so-called 'spot" receiving treatment. With respect to Figure 1, this means that the so-called 'range shifter" is no longer located in the region of exit window 11 but placed before the treatment arrangement 1, as Figure 4 shows schematically, specifically with reference number 31.

Placing the so-called "range shifter" before the following proton beam guiding device within the treatment arrangement does, however, have the effect that in conjunction with this design magnetic arrangements 7, or the magnet arrangement in the end-mounted proton beam guiding and control device housing 9, must be made variable in order to compensate for an increased or attenuated energy of the proton beam so that the proton beam may ultimately be in turn directed to the desired spot in the patient. However, this is no problem using the currently known process controls or known computer controls, while on the other hand the above-cited problems

connected with the precision of beam control may be significantly improved by simplifying the design of the exit window.

The usual procedure for the required destruction of the malignant cells in an organ or in a human body is to move the patient table relative to the proton beam guiding housing in discrete steps so as to allow the proton beam to scan the entire region in the organ or human body point by point. This motion of the patient table is necessary since the 'sweeper magnet" and 'range shifter" move the proton beam only in two directions, or two—dimensionally, so that the patient table must be designed to be movable to accommodate the spatial treatment of a region in a patient, or to accommodate the third dimension. With the selected spot—scanning method, this motion of the patient table is not continuous but occurs, as mentioned, in discrete steps. This discrete motion is often viewed as disadvantageous or awkward, especially by the attending physicians or persons providing treatment.

For this reason, another variant embodiment of the proton therapy device according to the invention proposes a covering housing in the region of the

exit window or so-called "nozzle" in which all the devices required for dosing and control or shielding, and elements for controlling the proton beam, are located out of sight. With respect to the motion, this housing itself is coupled to the patient table through a control device such that the discrete movements of the table are also effected by this covering housing and for the patient no relative motion with respect to the proton beam guiding housing occurs. An additional advantage of including such a covering housing is the fact that the relative position of a contact-hazard-protection device, which may be integrated with the housing, always ensures optimum protection in the event the patient table is to be moved relative to the exit window or the 'nozzle." Such a protection device may thus be located within the housing where it can interrupt the proton beam within fractions of a millisecond.

The advantage of including such a covering housing is also the fact that, for example, the collimators and compensators required for concentrating and focusing the proton beam in other known devices, for example, those using the so-called scattering method, may be located in such a housing. The controlled coupling of the covering with the patient table ensures in this case that even when the patient table is moved the proton beam always remains

directed at the proper spot in the body of the patient body.

With respect to Figure 1, this means that the housing 11 of the exit window, shown schematically, is not attached to proton beam guiding and control device 9 but is controlled to move also synchronously with the movements of the patient table. It is possible here to couple the movements of covering housing 11 with those of patient table 21 by using a control device so that no relative motions between the housing and the table take place when patient table 21 is moved during treatment of the patient.

The improvements proposed according to the invention for a proton beam treatment device, especially one utilizing the spot-scanning method such as the so-called 'gantry" at the Paul Scherrer Institute, result in significant simplifications in the operation of the device as well as enhancements in the safety and user acceptability of the device, both for patients as well as for the operating personnel.

Device for Administering a Proton Therapy

This invention relates to a device for administering proton therapy to human patients as well as various improvements designed to increase safety, to improve and simplify process control, to enhance patient acceptability, and also to allow the device to be constructed to smaller dimensions; the invention also relates to an application or a device

Proton therapy, especially that intended for the treatment of cancers, is becoming increasingly important since it entails significant advantages in comparison with the photon-radiation therapy in widespread use.

Although equipment for administering proton therapy has been known since the mid-fifties in the U.S., up to now such therapies have been utilized worldwide only at a few centers such as research institutions. This circumstance is due first to the fact that proton accelerators required are still quite expensive, and secondly to the fact that the proton therapy equipment necessary for administering an efficient and safe therapy is quite large and complex. The first and only purely hospital-based proton therapy device is located in the U.S. at the Loma Linda University Medical Center in California. Additional units are in the process of being put into operation in Boston (U.S.) and Kashiwa (Japan).

Unlike the above device at the Loma Linda University Medical Center in which the proton therapy is performed using a so-called scattering method, a proton therapy device was developed at the Paul Scherrer Institute in Würlingen, Switzerland, which utilizes the so-called spot-scanning method. In this

connection, reference is made to the article by Eros Pedroni et al. in Med. Phys. 22 (1), January 1995, pages 37-53 with the title "The 200-Mev Proton Therapy Project at the Paul Scherrer Institute: Conceptual Design and Practical Realization." This article refers to the fundamental principle of the above-mentioned spot-scanning method and to a device described using the term "gantry," with which device proton therapy has now been administered to patients for about three years . Although the outside dimensions of the device at the Paul Scherrer Institute were able to be reduced relative to the device at the Loma Linda University Medical Center by using the so-called spot-scanning method, this device still has a diameter of about 4 m, and has the additional disadvantage that access to patients during treatment is unsatisfactory. A detailed description of the device at the Paul Scherrer Institute may be dispensed with by citing the above reference in the literature, which reference is an integral part of the present patent application.

The preferred position for a patient is the supine position so as to preclude any deformation of the organs during treatment. Therapy must therefore allow accessibility from all sides and encompass the entire human body; for this reason, the generally known proton therapy devices, including that at the Paul Scherrer Institute, are designed so that the entire proton beam guiding device housing is rotatable 360° about a central axis around the so-called patient table, with the result that the device may have a diameter of between 4 and 12 meters. Especially when treating a patient from below, the proton beam guiding device must be moved under the patient table, or the patient table must be raised to a position several meters above the actual level of the working base. The resulting specific disadvantages may also be found in the above-cited literature

reference on page 49 in chapter IV, D4 which cites the problems entailed by raising the patient table in this way. This positioning process is critical, and in the event the device experiences an accident during treatment, a special crane device is required to extract or manage the patient. While this disadvantage may be alleviated by providing a relatively deep shaft under the patient table, this approach creates a risk of accidents, such as the person treating the patient falling into this shaft.

The object of this invention is thus to propose measures by which the operation of proton therapy may be simplified and made safer, and in which preferably the outside dimensions of the device may be reduced.

According to the invention, this object is achieved by a proton therapy device particularly according to Claim 1, and by means of using the proton therapy device according to Claim 11.

The invention proposes that a proton beam guiding and control device, or a proton beam guiding device housing located in the treatment arrangement, not be rotatable by a full 360° around a patient table, unlike the "gantry" of the Paul Scherrer Institute, described in the literature, but that the rotational movement be limited to approximately 270°. Here the rotation occurs essentially about a horizontal axis of rotation, in which axis of rotation generally a controllably movable patient table is located in the starting position. This limitation to 270° results in a region through which the beam guiding and control device is not freely movable, in which region the patient table is freely movable and always readily accessible. It is this accessibility to the patient table in particular which represents an essential improvement provided by this

invention since the person providing treatment may always access the patient without danger or obstruction.

The result of this preferred arrangement of the proton beam guiding and control device in which the device is rotatable starting from the horizontal plane running essentially through the axis of rotation both upwards and downwards by approximately 135° about the axis of rotation, or from - 90° to +180° from the vertical, is that the patient table is readily accessible from the opposite side. The patient table is thus freely movable within the above-mentioned horizontal plane or within a horizontal plane designed to run nearly parallel to this plane - for example, specifically rotatable by at least 180° about an axis which runs essentially through the isocenter of the proton beam guiding and control device. The isocenter is formed on the one hand by the proton beam exiting the proton beam guiding and control device, and on the other hand by the axis of rotation about which this device is rotatable.

The result of this arrangement according to the invention is first of all, as already mentioned, that the patient table is always readily accessible, and secondly that despite this accessibility treatment of the patient from all sides is possible since first of all treatment both from above and below is ensured, as is treatment from both sides, the treatment being enabled by rotating the patient table by 180°.

Preferred variant embodiments of the arrangement according to the invention are characterized in the dependent claims.

Applications of the arrangement according to the invention are characterized in Claims 11 *et seq*.

To provide a fuller understanding of the invention, an example of a proton beam treatment device according to the invention is described in more detail based on Figs. 1-3, wherein:

Figure 1 is a perspective view of a proton beam treatment device for treatment of a patient from the side.

Figure 2 shows the device in Figure 1 for treatment of a patient from above.

Figure 3 shows the device in Figure 1 for treatment of a patient from below.

Figure 1 shows in schematic and simplified form a device 1 for treating a patient using proton beam therapy. Here the proton beam 3 is directed by quadrupoles 5 and magnets 7 to the actual end-mounted proton beam guiding and control device 9. Located on the front face of this proton beam guiding and control device is an exit window 11 or so-called "nozzle" through which the proton beam exits and is directed to the patient. The proton beam may be deflected horizontally within a narrowly limited angle by an additional deflection magnet arrangement 6, also called a "sweeper magnet." At the same location, the drawings show a second "sweeper magnet" which may be used as an option to effect a rapid magnetic motion of the beam - but one which is limited by the aperture of the 90° magnet. Also located in the region of exit window 11 and not visible in Figure 1 is a penetration depth adjustment device, also called a "range shifter," by which the penetration depth of the proton beam into the body of the patient may be set. It is important here to again refer to the article by Pedroni et al. cited in the preamble which describes the basic principles of operation

for a proton beam therapy device such as the so-called "gantry" at the Paul Scherrer Institute.

Also shown in Figure 1 is a guide rail 13 on which is arranged the proton beam guiding and control device 9 so as to be movable about a central axis of rotation. Protruding through lateral shielding guides 15, the exit window 11 moves in a slit-like opening 17 along mounting device 13 when the guiding and control device (9) is moved.

A patient table 21 is arranged to lie in a horizontal plane, running essentially through the axis of rotation of the guiding and control device. This table is movable about an axis of rotation and on a mounting device 23 along a guide 24, this guide being located on a working platform 25. The rotation of patient table 21 proceeds preferably here about an axis of rotation which runs essentially through the head region 27 of patient table 21, and which axis of rotation runs mainly through the region of the so-called isocenter of the device. It is of course possible to have the horizontal plane in which the patient table 21 is located also run parallel a certain distance above or below the horizontal plane through which the rotational axis of proton beam guiding and control device 9 runs. This distance should be restricted, however, so as to ensure that proper treatment is possible from above and below, and additionally to allow the patient table to be capable of being accessed at a suitable height from working platform 25 by the person providing treatment. It is of course also possible to have patient table 21 be arranged on mounting device 23 so as to be both adjustable vertically and slidable in the longitudinal and transverse axes of the table.

The rotatability of the patient table should encompass an angle of at least 180°, although it is clearly evident from Figure 1 that an angle greater than 180° is not feasible for reasons of design and is also not necessary. According to another special variant embodiment, it is also possible to design the patient table to be rotatable about another axis of rotation, for example, around a vertical axis of rotation running through the center of the table. This rotation is necessary or useful, for example, when a patient is to be treated in the leg region and this region must thus be aligned with the isocenter of the device to allow, for example, a tumor in one leg to be treated accordingly by the proton beam.

Figure 2 shows the same device as in Figure 1 with beam guiding and control device 9 in the top orientation. In other words, in the arrangement of Figure 2 the proton beam treatment is administered from above, while in addition the patient table is in a position different from that in Figure 1. In addition, Figure 2 clearly shows that the patient table is slidable in the longitudinal axis of the table.

Finally Figure 3 shows yet another position attainable by beam guiding and control device 9 where treatment of the patient is administered from below.

The fundamental advantage of the device described according to the invention over the known "gantry" at the Paul Scherrer Institute is immediately evident in the fact that the patient table, for example, does not need to be raised significantly to administer treatments from below and that as a consequence accessibility to the patient table for the person providing treatment is always ensured. This feature has advantages not only for a patient receiving treatment but also for a person

providing treatment since with the device according to the invention there is no longer any risk of accidentally falling into a shaft.

An additional problem associated with existing proton treatment devices is encountered in the region of the exit window of the proton beam housing, also called the "nozzle" in English and in technical parlance. Located in the region of this exit window in the device described in the introduction above is a penetration depth adjustment device, also called a "range shifter" with which the penetration depth of the proton beam is controlled very precisely since the energy required to destroy a malignant organ or tumor is released precisely at the end of the range of the proton beam.

In practice it has been found that the proton beam is disturbed by the air gap between the so-called "range shifter" and the patient, thereby degrading the precision of beam control at least slightly.

For this reason, the invention also proposes locating this adjustment device for modifying the range of the proton beam, or the so-called "range shifter," no longer in the region of the output window or the so-called "nozzle" on the proton beam guiding housing, but instead before the entry of the proton beam into the guiding housing in which the proton beam is guided, in known fashion, to the patient and to the so-called "spot" receiving treatment. With respect to Figure 1, this means that the so-called "range shifter" is no longer located in the region of exit window 11 but placed before the treatment arrangement 1, as Figure 4 shows schematically, specifically with reference number 31.

Placing the so-called "range shifter" before the following proton beam guiding device within the treatment arrangement does, however, have the effect that in conjunction with this design magnetic arrangements 7, or the magnet arrangement in the end-mounted proton beam guiding and control device housing 9, must be made variable in order to compensate for an increased or attenuated energy of the proton beam so that the proton beam may ultimately be in turn directed to the desired spot in the patient. However, this is no problem using the currently known process controls or known computer controls, while on the other hand the above-cited problems connected with the precision of beam control may be significantly improved by simplifying the design of the exit window.

The usual procedure for the required destruction of the malignant cells in an organ or in a human body is to move the patient table relative to the proton beam guiding housing in discrete steps so as to allow the proton beam to scan the entire region in the organ or human body point by point. This motion of the patient table is necessary since the "sweeper magnet" and "range shifter" move the proton beam only in two directions, or two-dimensionally, so that the patient table must be designed to be movable to accommodate the spatial treatment of a region in a patient, or to accommodate the third dimension. With the selected spot-scanning method, this motion of the patient table is not continuous but occurs, as mentioned, in discrete steps. This discrete motion is often viewed as disadvantageous or awkward, especially by the attending physicians or persons providing treatment.

For this reason, another variant embodiment of the proton therapy device according to the invention proposes a covering housing in the region of the exit window or so-called "nozzle"

in which all the devices required for dosing and control or shielding, and elements for controlling the proton beam, are located out of sight. With respect to the motion, this housing itself is coupled to the patient table through a control device such that the discrete movements of the table are also effected by this covering housing and for the patient no relative motion with respect to the proton beam guiding housing occurs. An additional advantage of including such a covering housing is the fact that the relative position of a contact-hazard-protection device, which may be integrated with the housing, always ensures optimum protection in the event the patient table is to be moved relative to the exit window or the "nozzle." Such a protection device may thus be located within the housing where it can interrupt the proton beam within fractions of a millisecond.

The advantage of including such a covering housing is also the fact that, for example, the collimators and compensators required for concentrating and focusing the proton beam in other known devices, for example, those using the so-called scattering method, may be located in such a housing. The controlled coupling of the covering with the patient table ensures in this case that even when the patient table is moved the proton beam always remains directed at the proper spot in the body of the patient body.

With respect to Figure 1, this means that the housing 11 of the exit window, shown schematically, is not attached to proton beam guiding and control device 9 but is controlled to move also synchronously with the movements of the patient table. It is possible here to couple the movements of covering housing 11 with those of patient table 21 by using a control device so that no relative motions between the housing and the table take

place when patient table 21 is moved during treatment of the patient.

The improvements proposed according to the invention for a proton beam treatment device, especially one utilizing the spot-scanning method such as the so-called "gantry" at the Paul Scherrer Institute, result in significant simplifications in the operation of the device as well as enhancements in the safety and user acceptability of the device, both for patients as well as for the operating personnel.

Claims

1. Arrangement for treating a patient using proton therapy, comprising a proton beam guiding device employing magnets (7), quadrupoles (5), as well as an end-mounted proton beam guiding and control device (9) with an exit window (11) for guiding or directing the proton beam (3) to the treatment spot in the patient, as well as a controllably movable patient table (21) for moving the patient to the desired position relative to the proton beam, characterized in that the proton beam guiding and control device (9) is located so as to be turnable or rotatable by turning or rotating about a horizontal axis in such a way that the patient table located in essentially the plane of the axis of rotation remains accessible from the side, and characterized by rotating the patient table (21) in a horizontal plane running essentially through the axis of rotation or parallel to it and displaced by a small deviation around an axis which runs essentially through the isocenter of the arrangement, which isocenter is formed by the intersection of the proton beam with the axis of rotation or with the intersection by approximation of the beam with the axis of rotation.

2. Arrangement, especially according to Claim 1, characterized in that the beam guiding and control device (9) is arranged to be turnable or rotatable by at least 135° upwards and downwards from a horizontal plane running essentially through the axis of rotation.

3. Arrangement, especially according to Claim 1, characterized in that the beam guiding and control device (9) is arranged to be rotatable about the axis of rotation from a vertical plane

running essentially through the axis of rotation by an angle of 90° from the side of the vertical plane on which the patient table is located up to an angle of approximately 180° on the opposite side of the vertical plane.

4. Arrangement, especially according to Claim 1 or Claim 3, characterized in that the patient table (21) is arranged to be rotatable or movable in the region of the horizontal plane through which the beam guiding and control device (9) is not movable, or which region lies opposite the other region through which the beam guiding and control device (9) is movable.

5. Arrangement, especially according to Claims 1-4, characterized in that the patient table is preferably rotatable about an axis (27) in an end-mounted region on the patient table (21).

6. Arrangement, especially according to Claims 1-5, characterized in that the patient table is arranged to be slidable or movable in its longitudinal axis.

7. Arrangement, especially according to Claims 1-6, characterized in that the patient table is designed to be additionally rotatable about an axis running vertically in essentially the center region of the table, to be movable in a direction transverse to the longitudinal axis, and also to be adjustable in height.

8. Arrangement for treating a patient using proton therapy, comprising a proton beam guiding device employing magnets (6, 7), quadrupoles (5), and an end-mounted proton beam guiding and control device (9) with an exit window for directing the proton beam to the treatment spot in the patient, as well as a

controllably movable patient table (21) for moving the patient to the desired position relative to the proton beam (3), characterized in that a proton beam penetration depth adjustment device (31) is located in front of the arrangement before the magnets (7) and quadrupoles (5) and comprises a system of plates or blades movable in or through the proton beam so as to control or restrict the energy and the associated penetration depth of the proton beam in the patient.

9. Arrangement for treating a patient using proton therapy, comprising a proton beam guiding device employing magnets (7), quadrupoles (5), and an end-mounted proton beam guiding and control device (9) with an exit window for directing the proton beam to the treatment spot in the patient, as well as a controllably movable patient table (21) for moving the patient to the desired position relative to the proton beam (3), characterized in that the exit window (11), or a covering housing which is end-mounted on the proton beam guiding and control device and forms the exit window, is provided which is movement-coupled with the patient table (21) during treatment such that during treatment of the patient discrete movements effected by the patient table (21) are synchronously reproduced by the exit window or covering housing (11).

10. Arrangement, especially according to Claim 9, characterized in that an additional control device is provided for coupling the motion of the patient table (21) with the exit window or covering housing (11) during treatment of a patient.

11. Application of an arrangement according to one of Claims 1-10 for treating a patient using proton therapy, characterized in that a person lying on the patient table is positioned by moving the patient table and proton beam guiding and control

device such that the proton beam is directed to the treatment spot in the patient and that the patient table remains accessible at all times from one side.

12. Application, especially according to Claim 11, characterized in that the proton beam guiding and control device and the patient table are positioned around one axis - the proton beam guiding and control device by turning or rotating about a horizontal axis of rotation and the patient table by turning in a horizontal plane running essentially through the horizontal axis of rotation or parallel to this and arranged so as to be displaced by a small deviation - which one axis runs essentially through the isocenter of the arrangement, which isocenter is formed by the intersection of the proton beam with the axis of rotation or with the intersection by approximation of the beam with the axis of rotation.

13. Application, especially according to Claim 11 or Claim 12, characterized in that the energy, and associated with this, the penetration depth of the proton beam in the patient is controlled or restricted by means of a proton beam penetration adjustment device located in front of the arrangement before the magnets (7) and quadrupoles (5) and comprising a system of plates or blades movable in or through the proton beam.

14. Application according to one of Claims 11-13 for destroying a malignant organ or tumor in a human body.

(12) NACH DEM VERTRAG ÜBER DIE INTERNATIONALE ZUSAMMENARBEIT AUF DEM GEBIET DES PATENTWESENS (PCT) VERÖFFENTLICHTE INTERNATIONALE ANMELDUNG

(19) Weltorganisation für geistiges Eigentum
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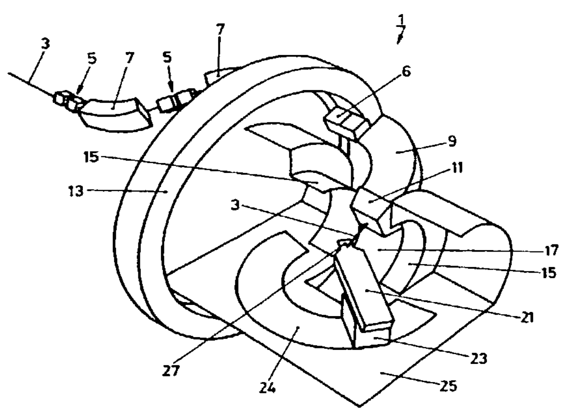
(81) Bestimmungsstaaten *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM,

[Fortsetzung auf der nächsten Seite]

(54) Title: DEVICE FOR CARRYING OUT PROTON THERAPY

(54) Bezeichnung: VORRICHTUNG ZUM DURCHFÜHREN EINER PROTONENTHERAPIE



(57) Abstract: A device for carrying out proton therapy on a patient, comprising means for guiding a proton beam using magnets (7) and quadripoles (5), in addition to an end-mounted device (9) for guiding and controlling the proton beam and which is provided with a beam hole (11) in order to guide or direct the proton beam (3) towards the point on the patient's body which is to be treated. A patient table (21) can be moved in a controlled manner in such a way that the patient can be placed in a desired position with respect to the proton beam. The proton beam guiding and controlling device (9) can be turnably or rotatably mounted around a horizontal axis of rotation in such a way that the patient table which is arranged approximately on the plane of the axis of rotation remains accessible from one side at all moments for the person treating the patient. The patient table (21) can de displaced slightly on a horizontal plane, extending inside the axis of rotation or parallel thereto, about an axis which runs approximately through the isocenter of the device, whereby said isocenter is formed by the intersection of the proton beam with the axis of rotation or the approximate point where the beam intersects with the axis of rotation. The inventive device is particularly suitable for use in the destruction of a sick organ or tumor in the human body.

(57) Zusammenfassung: Eine Anordnung zum Behandeln eines Patienten mittels Protonentherapie weist eine Protonenstrahlführung mittels Magneten (7), Quadrupolen (5) sowie eine endständige Protonenstrahlführungs-und-steuerungseinrichtung (9) mit einem Austrittsfenster (11) auf, um den Protonenstrahl (3) an die zu behandelnde Stelle im Patienten

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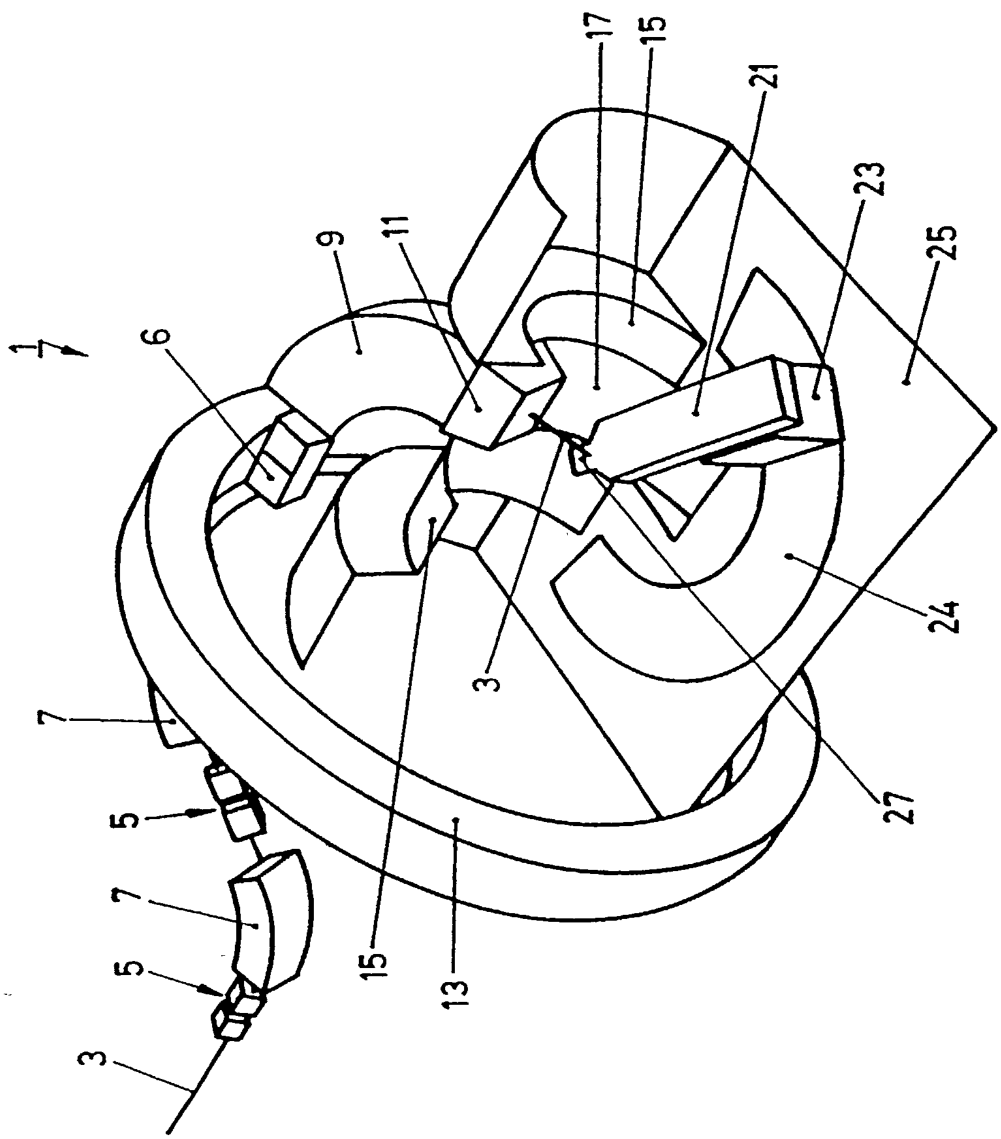

FIG.1

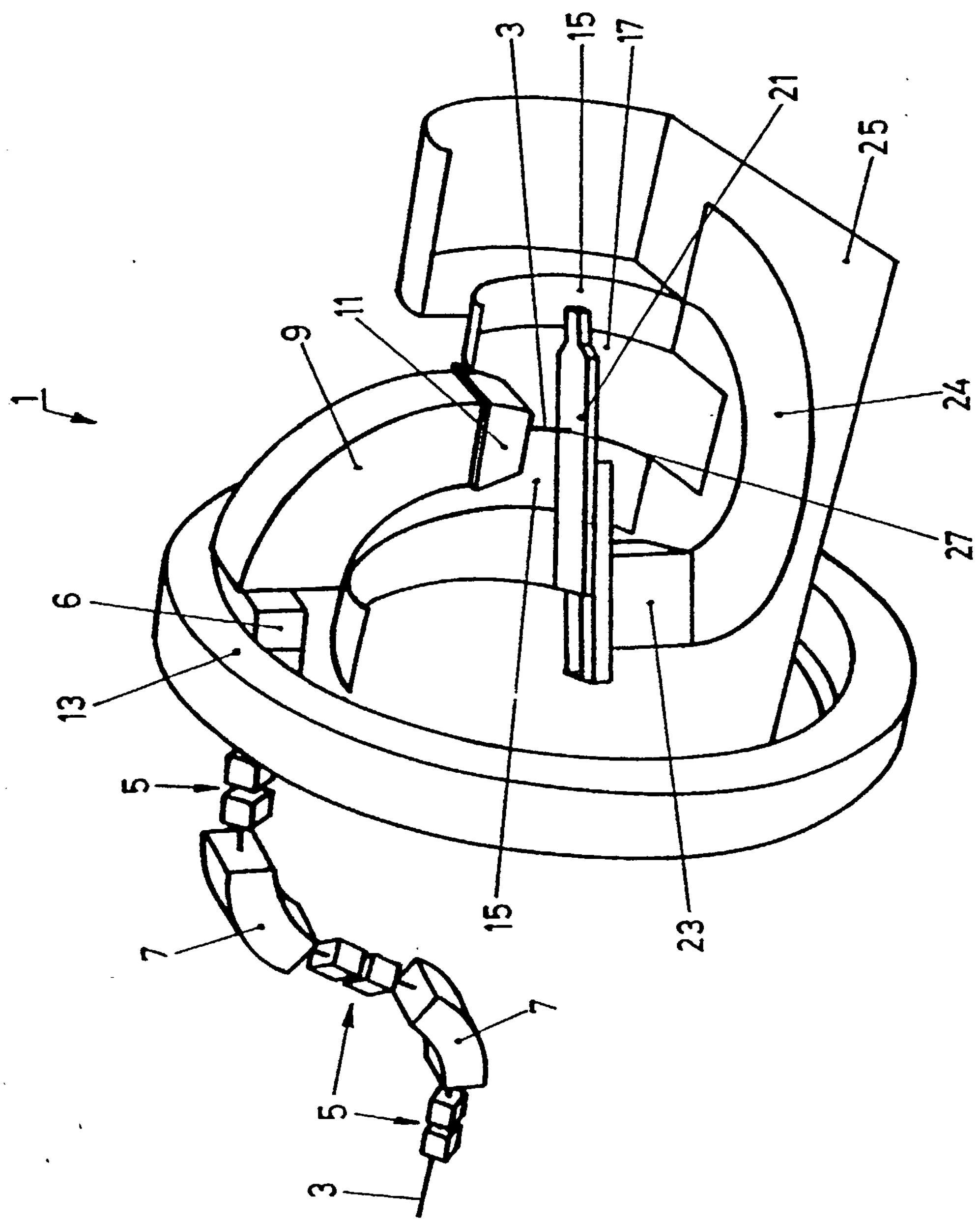

FIG.2

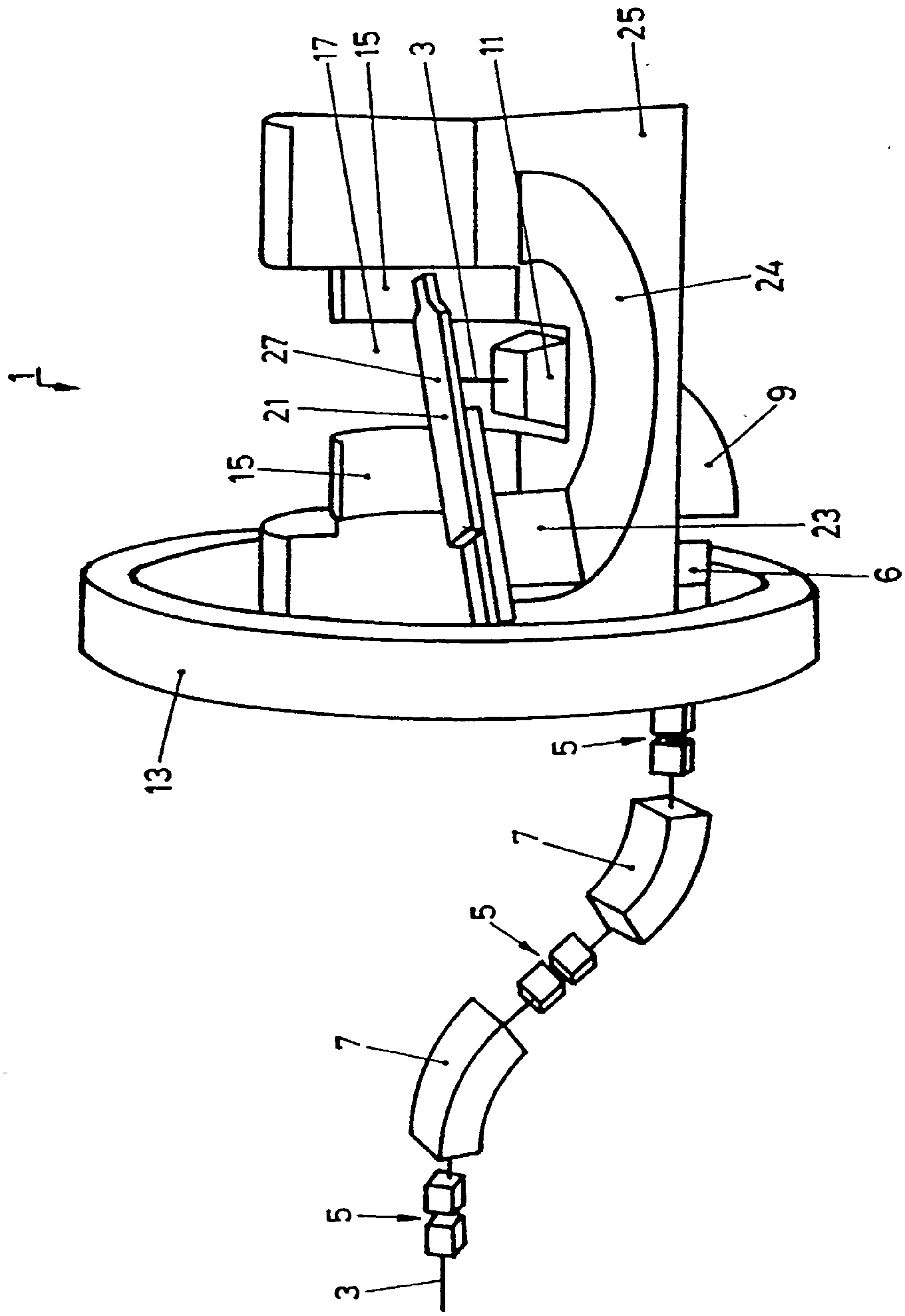

FIG.3

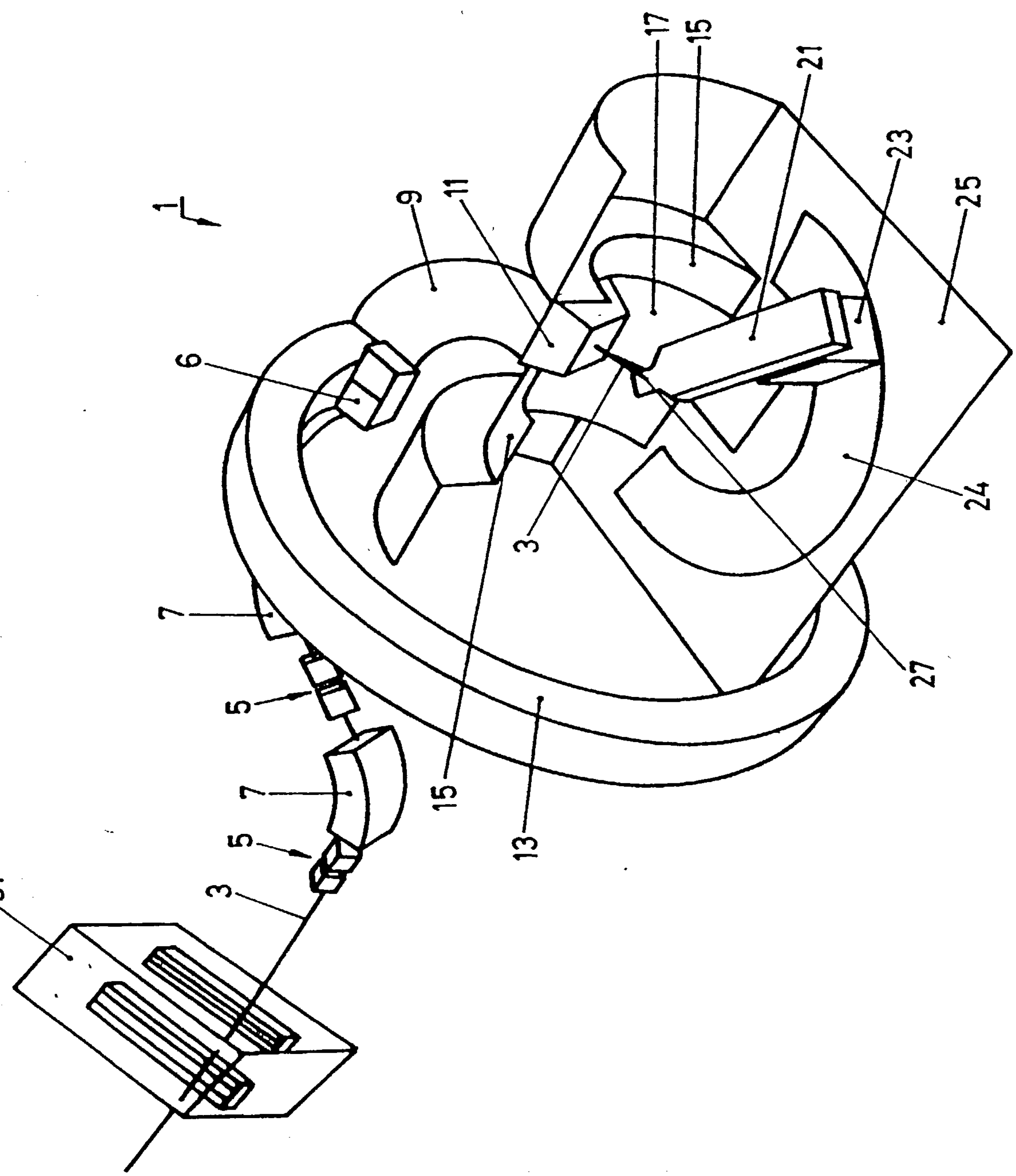

FIG.4

10018797 .062802 #5
P20125A US

Attorney's Docket No.: 635.40829X00

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that: my residence, post office address and country of citizenship are as stated below, next to my name; I believe I am the original, first, and sole inventor (if only one name is listed below) or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled **DEVICE FOR CARRYING OUT PROTON THERAPY**.

the specification of which

___ is attached hereto.

_x_ was filed on **December 21, 2001** as
United States Application Number **10/018,797**
or PCT International Application Number **PCT/CH00/00334**
and was amended on ______________________.
(if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above. I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits, under 35 U.S.C. 119(a)-(d) or 365(b), of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)

(Number)	(Country)	(Foreign Filing Date)	Priority Claimed? Yes	No
1180/99	Switzerland	25 June 1999	X	

I hereby claim the benefit, under 35 U.S.C. 119(e), of any United States provisional application(s) listed below:

(Application Number)	Filing Date

I hereby claim the benefit, under 35 U.S.C. 120, of any United States application(s) listed below:

(Application Number)	Filing Date	(Status -- patented, pending, abandoned)

I hereby appoint: Donald R. Antonelli, Reg. No. 20,296; Melvin Kraus, Reg. No. 22,466; William I. Solomon, Reg. No 28,565; Gregory E. Montone, Reg. No. 28,141; Ronald J. Shore, Reg. No. 28,577; Donald E. Stout, Reg. No. 26,422; Alan E. Schiavelli, Reg. No. 32,087; James N. Dresser, Reg. No. 22,973; Carl I. Brundidge, Reg. No. 29,621; Paul J. Skwierawski, Reg. No. 32,173; and Robert M. Bauer, Reg. No. 34,487; of ANTONELLI, TERRY, STOUT & KRAUS, LLP with offices located at 1300 North Seventeenth Street, Suite 1800, Arlington, Virginia 22209, my attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

1-00

Full Name of Sole/First Inventor **Eros PEDRONI**

Inventor's Signature E Pedroni Date 26.03.2002

Residence **Brugg, Switzerland** (City, State) Citizenship **Switzerland** (Country of Citizenship) CH X

Mailing Address **Erienweg 19, CH-5200 Brugg/Switzerland**

Title 37, Code of Federal Regulations, Section 1.56
Duty to Disclose Information Material to Patentability

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclosure information exists with respect to each pending claim until the claim is cancelled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is cancelled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclosure all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by ¤¤1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) Prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) The closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made or record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application;

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

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PTO/SB/122 (11-96)
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Application Number	10/018797
Filing Date	December 21, 2001
First Named Inventor	PEDRONI, Eros
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Examiner Name	
Attorney Docket Number	635.40829X00

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Signature	Ronald J Shore
Date	December 21, 2001